K032760

SEP 17 2003

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Company and Correspondent making the submission:

Name – TIS, Inc..
Address – Suite 602, KWTC, 159-1, Samsung-Dong, Kangnam-Ku, Seoul, 135-729, Korea
Telephone – +82-2-6000-8869
Fax – +82-2-6000-8868
Contact – Mr. Sung Ho Byun
Internet – http://www.tis21.com

2. Device :

Proprietary Name – APAX™
Common Name – Picture archiving and communication system
Classification Name – Picture archiving and communication system

3. Predicate Device :

Mediface Co., Ltd.
Mediface PACS™ System
K010259

4. Classifications Names & Citations :

21CFR 820.2050, LLZ, Picture archiving and communication system, Class2 Guidance document for the preparation of premarket notifications [510(k)'s].

5. Description :

The APAX™ PACS system is a general purpose software designed for acquisition/ capture/ view/ archival and transmission of medical images. This device allows easy capturing, selection, review, processing and filming of multi-modality DICOM images from a variety of diagnosis imaging systems such as MRI, CT, CR, etc., and of non-DICOM images from Ultrasound (by capturing) and X-ray Film (by scanning). When interpreted by a trained

physician, filmed images may be used as a basis for a diagnosis. The PACS system

The APAX™ PACS is intended to be used by authorized staff to perform medical image management, communications, storage, archiving and review. Images and data can be stored, transmitted (communicated), processed at the workstation, physician's desktop or other clinical application and distributed across networks or the world wide web. Typical users are trained professionals, including not limited to physicians, nurses, and technicians.

6. Indication for use :

The APAX™ PACS is intended to be used by authorized staff to perform medical image management, communications, storage, archiving and review. Images and data can be stored, transmitted (communicated), processed at the workstation, physician's desktop or other clinical application and distributed across networks or the world wide web. Typical users are trained professionals, including not limited to physicians, nurses, and technicians.

7. Comparison with predicate device :

TIS, Inc., believes that the APAX™ PACS System is substantially equivalent to the Mediface PACS™ System.

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification TIS, Inc.. concludes that APAX™ is safe and effective and substantially equivalent to predicate devices as described herein.

10. TIS, Inc.. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

TIS, Inc.
% Mr. Marc M. Mouser
Office Coordinator
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K032760
Trade/Device Name: APAX™ PACS System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 25, 2003
Received: September 5, 2003

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032760

Device Name: APAX™ PACS System

Indications for Use:

The Device is intended to be used by authorized staff to perform medical image management, communications, storage, archiving and review. Images and data can be stored, transmitted (communicated), processed at the workstation, physician's desktop or other clinical application and distributed across networks or the world wide web. Typical users are trained professionals, including not limited to physicians, nurses, and technicians.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032760